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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,266	09/13/2005	Hans Stoop	97086-00064	1656

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EXAMINER	
WERNER, JONATHAN S	

ART UNIT	PAPER NUMBER
3732	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,266	STOOP, HANS	
	Examiner	Art Unit	
	Jonathan Werner	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,11,12,14 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,11,12,14 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to Applicant's amendment received 8/16/07.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 9, 11-12 and 14-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 9, Applicant claims the step cutting edges of each drill are "sharply formed." However, Examiner cannot find any support for this limitation in the originally filed specification. The original claim 9 stated that the step cutting edges are "formed in a cutting manner," thus implying that the process for creating said cutting edges was carried out by cutting them. Examiner understood this type of recitation to be a product-by-process limitation, which is in stark contrast to the currently amended claim limitation, which, as discussed below in the rejection under 35 U.S.C. 112, second paragraph, can be interpreted either as meaning the cutting edges have a sharp form (for which Examiner cannot find proper support in the specification), or that they are formed from a sharp cutting process (which would remain a product-by-process limitation). Similarly, Applicant claims the guide cutting

edges of each drill are "bluntly formed." However, Examiner cannot find any support for this limitation in the originally filed specification. The original claim 9 stated that the guide cutting edges are "formed in a blunt, non-cutting manner," thus implying that the process for creating said cutting edges was carried out, for example, in the absence of a sharp cutting tool. Examiner understood this type of recitation to be a product-by-process limitation, which is in stark contrast to the currently amended claim limitation, which, as discussed below in the rejection under 35 U.S.C. 112, second paragraph, can be interpreted either as meaning the cutting edges have a blunt form (for which Examiner cannot find proper support in the specification), or that they are formed from a blunt, non-cutting process (which would remain a product-by-process limitation).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 9, 11-12 and 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 9, Applicant has claimed that the step cutting edges of the respective drills are "sharply formed." It is not clear whether Applicant means that the cutting edges themselves are sharp, or if they have been created in a cutting manner, as described in the specification. Similarly, Applicant has claimed that the guide cutting edges of the respective drills are "bluntly formed." It is not clear whether Applicant means that the cutting edges themselves are blunt, or if

they have been created in a non-cutting manner, as described in the specification. If Applicant has intended the step cutting edges or the guide cutting edges to define a structurally sharp or blunt surface, respectively, then Examiner suggests positively claiming said structure instead of the way it is formed. As presently interpreted, however, Examiner will understand each limitation describing forming both the guide and step cutting edges to be directed to product-by-process type limitations, wherein the article of manufacture (i.e. each cutting edge) is claimed, and not the process of forming/making the device (i.e. in a sharp or blunt manner).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 9, 11-12 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guedj (US 5,871,356) in view of Bradley (US 3,564,945).

5. Guedj discloses a drill that is capable of being used either as a pilot drill or a step drill in a drilling procedure to create a hole for receiving a dental implant, in which Figures 8 and 9 show the drill comprises a chamfered pilot tip at the apical end with cutting edges, a step which transitions from the guide region (portion to the left of the step) to the neck (portion to the right of the step), wherein said neck region is shown to

have a larger diameter than the guide portion, and wherein Figure 8 demonstrates the step and guide each has a cutting edge. Figures 8 and 9 also clearly show a drill stem (24) above the neck which is adjoined by a coupling (rightmost projection next to said stem), and at least one spiral groove with adjacent bevels. Guedj additionally discloses the drill has various tip/neck diameters and lengths (i.e. column 2, lines 19-23).

6. Furthermore, Guedj shows in Figures 8 and 9 that the drill has two cutting edges and has two tip cutting edges, two chamfers, two spirals that extend continuously from the coronal end of the neck to the tip, two step cutting edges, two bevels, and a number of visible depth markings characterized in the differing shape of each segment of the drill. Guedj also discloses that the drill can have a guide diameter in the region of 1.5 mm and a neck diameter in the region of 2.0 mm (column 6, lines 35-47) wherein the specific size is dependent on the external diameter of the dental implant eventually to be used. However, Guedj does not explicitly disclose a guide length from 1.0 to 4.0 mm or that the tip angle is in the region of 80°. Still, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to make the guide have a length of between 1.0 to 4.0 mm or the tip angle approximately 80° since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.* In this case, Examiner notes that the appropriate size required for the drill is dependent on the size of the implant to later be installed. Examiner notes that in regard to claim 14, Guedj does show in Figure 8 that the drill has three cutting

edges, three tip cutting edges, three chamfers, three guide cutting edges, three spirals, three bevels, and wherein the tip angle is more than 90° as shown in Figure 9.

7. Though Guedj shows the specifics of the particular drill being claimed as described in detail above, Guedj fails to explicitly disclose the use of a drill set comprising a collection of different sized drills. Bradley, however, discloses a set of similar step drills provided together, wherein each successive drill in the set has increased dimensions (column 3, lines 53-61). Therefore, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to provide a set of drills each having differing dimensions in order to have a desired cutting head for a wide range of sizes as taught by Applicant, whereby the different sizes can account for various size implants. With regard to claims 12 and 15, Examiner notes Applicant has claimed statements of intended use, i.e. the drill works to produce an adequate implant site for a dental implant. Such statements of intended use and other functional statements do not impose any further structural limitations on the device claims distinguishable over the prior art of record, which is capable of being used as desired to create a hole for a dental implant (see Figure 10), and accordingly, are given little patentable weight. Examiner again notes that Applicant is claiming an article of manufacture, however, in certain steps, Applicant claims the process of forming/making the device, i.e. how the step and guide cutting edges are sharply or bluntly formed, respectively. Accordingly, the manner in which the device is formed, i.e. sharply or bluntly, is treated as a product-by-process limitation and hence given little patentable

weight since the cutting edges shown by Guedj in Figures 8 and 9 are similarly used for cutting purposes.

Response to Arguments

8. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. Applicant has amended the claims in such a way as to create confusion regarding the step cutting edges and guide cutting edges of the drill (discussed in detail in the rejections under 35 U.S.C. 112 above). It is unclear to the Examiner whether the newly presented claim recitation describing said cutting edges (i.e. how they are sharply or bluntly formed) was meant to be a product-by-process limitation as interpreted by the Examiner, or a defining structural limitation of the drill edge.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan Werner whose telephone number is (571) 272-2767. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on (571) 272-4964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jonathan Werner
Examiner

10/22/07

Melba Bumgarner
MELBA N. BUMGARNER
PRIMARY EXAMINER